HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1262 B

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

WARNING LETTER

March 17, 1997

Cin 97-282

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Vicki Huber
Vice President of Patient Services
Blanchard Valley Regional Health Center-Bluffton
139 Garau St.
P.O. Box 48
Bluffton, OH 45817-0048

Facility I.D.# 103572

Dear Ms. Huber:

Your facility was inspected on March 13, 1997 by a representative from the State of Ohio radiation control program under contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

> Your records lack the required information that [redacted] a medical physicist is qualified to perform quality assurance survey of your facility. Your records did not demonstrate that [redacted] is state licensed or state approved as a medical physicist or has either board certification from any of the approved organizations or the requisite education, training and experience.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

The other item listed in your March 13, 1997 inspection report identified as Level 3 should also be corrected. We will verify correction of this item during our next inspection and you are not required to address this in your written response.

The March 13, 1997 inspection also revealed that your facility had a resurvey performed by a medical physicist on March 11, 1997. This resurvey was performed by a medical physicist of which your facility has adequate records of his qualification. This resurvey was performed outside of the fourteen (14) months time period since the last qualified medical physicist survey.

It is the responsibility of the mammography facility to demonstrate that a medical physicist survey be performed annually. This survey shall be performed on the premises by a qualified medical physicist.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, **or each day** of failure to substantially comply with, the Standards.

- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.

- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct all of the violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations; and

- sample records that demonstrate proper record keeping procedures, if the noncompliances that were found relate to quality control or other records (Note: **Patient names or identification should be deleted from any copies submitted).**

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

R. Terry Bolen
MQSA Radiological Health Officer
Food and Drug Administration
1141 Central Parkway
Cincinnati, OH 45202.

Also, send a copy to the State radiation control office:

Ms. Cynthia L. Grant
Ohio Department of Health
Oliver R. Ocasek
Government Office Building
161 S. High St., Suite 400
Akron, OH 44308-1616

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Terry Bolen at (513)684-3501, extension 138.

Sincerely yours,

John R. Marzilli
District Director
Cincinnati District Office

c.
OH/CLGrant